K033156

DEC - 9 2003

510(k) Summary of safety and effectiveness information for equivalence determination.

Device	OB1 Obstetrical Doppler
Common Name	Handheld Fetal Doppler
Manufacturer	D. E. Hokanson, Inc. 12840 NE 21st Place Bellevue, WA 98005 Phone: (425) 882-1689 Fax: (425) 881-1636
Establishment Registration Number	3019130
Contact	D. Eugene Hokanson, President
Preparation Date	September 26, 2003
Classification	Class II per FR 884.2660, Fetal Ultrasonic Monitor
Indications for Use	This product will be used to detect fetal heartbeats to help determine fetal viability.
Description	OB1 Obstetrical Doppler is a handheld, internally-powered Doppler audio instrument used for detecting fetal heart beats. There are only four user controls; Up and Down audio volume, Freeze Display, and Power On/Off. A three inch loudspeaker provides good Doppler audio. A digital LCD readout shows the fetal heart rate when it is stable for three or four seconds.
Substantial Equivalence to Predicate Devices	Huntleigh Technologies, Manalapan, NJ Dopplex II Pocket Doppler, K930200, cleared 6/24/94 Medasonics Incorporated, Newark, CA Cadance Doppler Ultrasound System, K991441, cleared 12/28/99 Summit Doppler Systems, Inc., Arvada, CO LifeDop Doppler Ultrasound System, K024197, cleared 1/03/03
Technology Summary	Doppler ultrasound technology in the OB1 is substantially equivalent to that in the predicate devices listed above. Recursive filter techniques are used to detect the fetal heart rate displayed on the digital readout. This achieves similar results as the techniques (not published) in the predicate devices.
Conclusion	Based on comparisons of device features, materials, intended use and performance, the OB1 Obstetrical Doppler is substantially equivalent to the commercially available and legally marketed devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2003

Mr. D. Eugene Hokanson
President
D. E. Hokanson, Inc.
12840 Northeast 21st Place
BELLEVUE WA 98005

Re: K033156
Trade Name: OB1 Obstetrical Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: 85 KNG
Dated: November 11, 2003
Received: November 17, 2003

Dear Mr. Hokanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the OB1 Obstetrical Doppler, as described in your premarket notification:

Transducer Model Number

2.25 MHz CW Fetal Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

2.25 MHz CW Fetal Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal										
Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Although the transducer can be disconnected from the main unit there is only a 2.25MHz probe available for the OB1 at this time.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) ✓

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K033156